

POMERANTZ LLP

Jeremy A. Lieberman
Managing Partner

August 28, 2017

VIA ECF

Hon. J. Paul Oetken, U.S.D.J.
Southern District of New York
Thurgood Marshall United States Courthouse
40 Foley Square, Courtroom 706
New York, NY 10007

Re: *In re Mylan N.V. Securities Litigation*, 16-cv-07926 (JPO)

Dear Judge Oetken:

We are counsel for Lead Plaintiffs (“Plaintiffs”) in the above-referenced action (the “Action”).¹ We write to request that the Court take judicial notice of certain documents relevant to Defendants’ pending motion to dismiss (the “Motion to Dismiss” or “Motion”) the amended complaint in the Action (the “Amended Complaint”). These documents include August 17, 2017 press releases from Mylan and the Department of Justice (“DOJ”) announcing the finalization of a \$465 million settlement related to Mylan’s misclassification of the EpiPen (enclosed hereto as Exhibits A and B, respectively), as well as a *qui tam* complaint by relator Ven-A-Care (enclosed hereto as Exhibit C), which was settled as part of the DOJ settlement and is now unsealed. These documents provide significant support for Lead Plaintiffs’ allegations that Mylan knowingly misclassified EpiPen during the Class Period. Alternatively, in the event the Court is inclined to grant Defendants’ Motion, we respectfully request that the Court grant Plaintiffs leave to amend the Amended Complaint in order to allow Lead Plaintiffs to include allegations from these documents.

A. The Court May Take Judicial Notice of Public Complaints and Press Releases in Deciding a Motion to Dismiss

Under Federal Rule of Evidence 201(b)(2), the Court may take judicial notice of facts “capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned,” including facts from documents submitted by plaintiffs in support of their opposition to a Rule 12(b)(6) motion to dismiss. *See HB v. Monroe Woodbury Cent. Sch. Dist.*, No. 11-CV-5881 (CS), 2012 U.S. Dist. LEXIS 141252, at *12-14 (S.D.N.Y. Sept. 27, 2012) (“Plaintiffs have submitted [certain] documents in conjunction with their opposition to

¹ Capitalized terms not defined in this letter shall have the definitions given to them in the Amended Complaint or the Opposition.

jalieberman@pomlaw.com

600 Third Avenue, New York, New York 10016 tel: 212.661.1100 www.pomerantzlaw.com

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Defendants' Motion . . . and I will consider [these documents] for the purposes of deciding the 12(b)(6) Motion"); *see also* Fed. R. Evid. 201(d) ("Judicial notice may be taken at any stage of the proceeding."). In particular, the Court may take judicial notice of prior complaints. *See Blue Tree Hotels Inv. (Canada), Ltd. v. Starwood Hotels & Resorts Worldwide, Inc.*, 369 F.3d 212, 217 (2d Cir. 2004) (Courts may take judicial notice of "public records" including "complaints"); *LC Capital Partners, LP v. Frontier Ins. Group, Inc.*, 318 F.3d 148, 153-55 (2d Cir. 2003) (permitting judicial notice of prior litigation filings). The Court also may take judicial notice of a press release, at a minimum for the fact of its publication. *See e.g., LC Capital Partners*, 318 F.3d at 153-55 (permitting judicial notice of press releases); *Floyd v. City of N.Y.*, 302 F.R.D. 69, 77 n.3 (S.D.N.Y. 2014) (taking judicial notice of defendant's own press release) *Stepski v. M/V Norasia Alya*, No. 7:06-cv-01694, 2010 U.S. Dist. LEXIS 16602, at *15 (S.D.N.Y. Jan. 14, 2010) ("the Court may take judicial notice of a government-issued press release as a matter of public record").

Here, the Court may take judicial notice of Exhibits A and B because they are press releases. *See id.* The releases were issued concurrently by Mylan (the "Mylan Press Release") and the DOJ (the "DOJ Press Release") on August 17, 2017 and are currently available on their websites.² The Court likewise may take judicial notice of Exhibit C because it is a prior litigation filing, namely, the First Amended Complaint in *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Mylan Inc.*, No. 17-10140 (D. Mass. Jan. 1, 2017) ("*Ven-A-Care Complaint*").

B. The Mylan and DOJ Press Releases and the *Ven-A-Care* Complaint Demonstrate That Mylan Misclassified the EpiPen and Knew That It Was Misclassified During the Class Period

On August 17, 2017, Mylan finalized an agreement with the DOJ to pay \$465 million to settle the government's claims that Mylan misclassified the EpiPen to overcharge Medicaid by up to \$1.27 billion. Mylan announced this settlement in the Mylan Press Release. The settlement agreement identified the civil actions being settled (both *qui tam* actions under the False Claims Act, 31 U.S.C. § 3730(b)), and the complaint in one of those actions, the *Ven-A-Care* Complaint, was unsealed. These documents provide even further support to the allegations

² Mylan N.V., *Mylan Finalizes Settlement Agreement on Medicaid Rebate Classification for EpiPen® Auto-Injector* (Aug. 17, 2017), available at <http://newsroom.mylan.com/2017-08-17-Mylan-Finalizes-Settlement-Agreement-on-Medicaid-Rebate-Classification-for-EpiPen-R-Auto-Injector> (last visited Aug. 28, 2017); Dept. of Just., Off. of Pub. Aff., *Mylan Agrees to Pay \$465 Million to Resolve False Claims Act Liability for Underpaying EpiPen Rebates* (Aug. 17, 2017), available at <https://www.justice.gov/opa/pr/mylan-agrees-pay-465-million-resolve-false-claims-act-liability-underpaying-epipen-rebates>.

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in the Amended Complaint and to Plaintiffs' arguments in their Opposition brief in at least three ways.

First, in the Mylan Press Release, Mylan admits that the EpiPen was misclassified. As explained in the Amended Complaint, Mylan misclassified its most important drug, the EpiPen, for the purposes of the MDRP throughout the Class Period, yet misled investors to believe the drug was correctly classified. (Am. Compl. ¶¶ 57-77.) Mylan does not contest in its Motion to Dismiss that the EpiPen was misclassified, or that its EpiPen Misclassification Omissions were misleading, and so concedes the falsity of these omissions. (See Opp. 8.) However, in the Mylan Press Release, Mylan *publicly admits* that the EpiPen was misclassified by agreeing to reclassify the EpiPen as a brand-name “innovator” drug. The Press Release states, “Mylan will reclassify EpiPen Auto-Injector for purposes of the Medicaid Drug Rebate Program and pay the rebate applicable to innovator products effective as of April 1, 2017.” This admission removes any seeds of doubt that Mylan might have been attempting to sow through silence about whether the EpiPen was misclassified under the laws and regulations governing classification for the purposes of the MDRP—Mylan now publicly acknowledges that the EpiPen was misclassified. Indeed, the statutory requirements for classification of EpiPen have not changed at all since the enactment of the statute governing MDRP classification. *See* 42 U.S.C. § 1396r-8 *et seq.* Accordingly, the only plausible conclusion to draw from the EpiPen reclassification as part of the DOJ settlement is that the Company acknowledges that EpiPen was misclassified during the Class Period, and is therefore changing that classification now.

Second, the DOJ Press Release makes clear that the DOJ had grounds, uncovered through its investigation, to allege that Mylan “knowingly misclassif[ied]” the EpiPen “to avoid paying rebates owed primarily to Medicaid.” The DOJ Press Release quotes Acting U.S. Attorney for the District of Massachusetts, William D. Weinreb, a lead attorney on the matter, as stating, “Mylan misclassified its brand name drug, EpiPen, to profit at the expense of the Medicaid program.” Likewise, in summarizing the DOJ’s allegations, the Press Release states: “The government further alleged that although Mylan was well-aware that its drug was not a generic, it nevertheless claimed generic status for EpiPen in the Medicaid program to avoid paying a higher rebate.”

Third, the *Ven-A-Care* Complaint alleges *direct* evidence that Mylan and its executives knew that EpiPen was misclassified. The *Ven-A-Care* Complaint discusses information obtained by the relator in that action through discovery taken from Mylan in a previous *qui tam* action, in particular “non-public depositions and litigation communications” from Mylan executives. Based on that discovery, *Ven-A-Care* alleges that Mylan executives, including former CFO Pamela Marrs, knew that:

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“Mylan was required to report, for Medicaid Rebate purposes, that a combination pharmaceutical product originally marketed under a New Drug Application [*e.g.*, EpiPen] was an innovator or single source product subject to the higher rebate amount, at least unless CMS had issued a written authorization for the specific pharmaceutical product designated in the written authorization.

(Ven-A-Care Compl. ¶ 66.) As is clear from the Amended Complaint and as stated in Plaintiffs’ Opposition, Mylan had no such written authorization. (Am. Compl. ¶¶ 50-51 & n.22; Opp. 15-16.)

Defendants contend in their Motion to Dismiss that a letter from 1997 authorized them not to classify the EpiPen as an innovator drug. (Defs.’ Mem. 3 & n.2.) Yet even if the Court could take judicial notice of the document on which they appear to rely, *i.e.*, Exhibit A to Plaintiffs’ Opposition (the “Purported 1997 Letter”), which it cannot (*see* Opp. 15 n.14), that letter designates the specific products and associated National Drug Codes to which it applies, namely “0301-01, 0302-01, 0302-01 and 0304-01 under labeler number 00268.” As explained in the Amended Complaint and in the *Ven-A-Care* Complaint, by 2009 (within a couple of years after Mylan acquired the EpiPen in 2007), Mylan had altered the EpiPen through patented changes that rendered the new product, in Mylan’s words, “substantially different” from the product designated in the Purported 1997 Letter. (Am. Compl. ¶¶ 66-71; Ven-A-Care Compl. ¶ 52.) Federal regulations required Mylan to alter the National Drug Code for the EpiPen “[i]f any change occur[ed] in those product characteristics that clearly distinguish[ed] one drug product version from another” 21 C.F.R. § 207.35. Accordingly, Mylan was required to change the National Drug Codes associated with the EpiPen, and while Mylan failed to make these legally required changes, the National Drug Codes in the Purported 1997 Letter ceased to apply to EpiPen by 2009, along with any authorization in the Purported 1997 Letter.

Indeed, the “non-public depositions and litigation communications” from Mylan executives, as relayed in the *Ven-A-Care* Complaint, make clear that Mylan executives fully understood that any authorization in the Purported 1997 Letter ceased to apply to EpiPen as early as 2009, thereby necessitating reclassification as an “innovator” drug.

“Mylan was aware that, once it discontinued the old combination products described in the [Purported 1997 Letter], and began to market newly patented substantially different products approved by the FDA pursuant to an NDA, it had a duty to pay the higher rebate for innovator and single source drugs.”

(Ven-A-Care Compl. ¶ 62). Accordingly, the *Ven-A-Care* Complaint cements the conclusion that Mylan and its executives knew the EpiPen was misclassified during the Class Period.

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C. While Defendants' Motion To Dismiss Should Be Denied in Its Entirety, Should the Court Grant Defendants' Motion, Plaintiffs' Request That the Court Grant Plaintiffs Leave to Amend the Complaint To Include These New Facts

As explained above, the Court may take judicial notice of Exhibits A, B and C in ruling on Defendants' Motion to Dismiss. *See HB*, 2012 U.S. Dist. LEXIS 141252, at *12-14. Alternatively, in the event this Court grants Defendants' Motion, Plaintiffs respectfully request that the Court grant Plaintiffs leave to amend the Amended Complaint, and that the Court consider these documents in ruling on that request.³

Respectfully Submitted,

By: /s/ Jeremy A. Lieberman
Jeremy A. Lieberman
Austin P. Van
POMERANTZ LLP
600 Third Avenue, 20th Floor
New York, New York 10016
Telephone: (212) 661-1100
jalieberman@pomlaw.com
avan@pomlaw.com

Steve J. Toll
Daniel S. Sommers
Times Wang
COHEN MILSTEIN SELLERS & TOLL PLLC
1100 New York Avenue, N.W.
West Tower, Suite 500
Washington, DC 20005-3964
Tel.: (202) 408-4600
Fax: (202) 408-4699
Email: stoll@cohenmilstein.com
dsommers@cohenmilstein.com
twang@cohenmilstein.com

³ Indeed, Plaintiffs also request that the Court grant leave to amend the Amended Complaint in the event the Court does take judicial notice of Exhibits A, B and C, yet nevertheless dismisses the Complaint, as additional supporting facts have come to light since the filing of the Amended Complaint beyond those contained in these documents.

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Laura H. Posner
COHEN MILSTEIN SELLERS & TOLL PLLC
88 Pine Street
14th Floor
New York, NY 10005
Tel.: (212) 838-7797
Fax: (212) 838-7745
Email: lposner@cohenmilstein.com

Attorneys for Lead Plaintiffs

cc: All counsel of record (via ECF)